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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,760	08/07/2001	Milan Mrksich	7814/45	1390

7590

01/14/2004

BRINKS HOFER GILSON & LIONE  
P.O. BOX 10395  
CHICAGO, IL 60610

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/14/2004

13

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/923,760

Applicant(s)

MRKSICH ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-117 is/are pending in the application.
- 4a) Of the above claim(s) 1-35 and 40-117 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

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**1)** The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

**2)** Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

**3)** Claims 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**a)** The use of the term "a reaction product ...on said substrate" renders claim 36 indefinite. It is unclear from the claim language whether the "reaction product" is oriented with the "reactant ligand" portion adjacent to ("on") the "substrate" or whether the "fusion polypeptide" portion of the "reaction product" is adjacent to the "substrate". It is also unclear by what means the "reaction product" is attached to (i.e. "on") the "substrate" (e.g. simply layered, covalent attachment, hydrogen bonding, etc.).

**b)** For claim 38, it is unclear whether the designation of the moiety "-Q-Z" being "on" the surface indicates that there is necessarily a covalent bond involved between "-Q-Z" and the surface. If there is such a covalent bond present, it is unclear what moiety on the "surface" the "-Q-Z" group is attached to. See also, the similar problems for claims 37 and 39.

**c)** It is unclear what is meant by the term "a reaction product of a reactant ligand and a fusion polypeptide". Page 13, lines 8-22 of the specification generically describes the formation of a "covalent" bond between the "reactant ligand" and the "capture polypeptide" but fails to describe the moieties which react and the chemical nature of the bond formed.

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4) Claims 36-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement and written description requirements. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a) The specification fails to provide an enabling written description to support any method of preparation of the protein chips of the instant claims. The written disclosure of page 38, lines 8-30 of the specification, "*Immobilization of reactant ligands*", describes in very generic terms several methods of immobilizing reactant ligands including references to "chemically modified with a linking group" which linking group may contain "a polymerizable group", a "diene or a dienophile", "an amine moiety" or "a thiol". However, this section of the specification fails to concretely describe the specific reactants involved, including appropriate "linking groups" and the reaction products produced by any such "immobilization". Further, although this section of the specification indicates that the "reactant ligand" portion of the "reaction product" is immobilized directly on the "surface" (see also the specification at page 8, lines 8 and 9), claim 36 includes the case in which the "fusion polypeptide" is immobilized directly on the "surface". There is no enabling written description in the specification of this type of immobilization.

b) The claims include specific cases for which there is no enabling written description in the specification, for example, for the case wherein  $Q = -CH_2-$  of claim 38. There is no enabling written description in the specification for the direct attachment of a "reaction product" "Z" through a  $-CH_2-$  moiety (or any other moiety defined by "Q" in claim 38) in the absence of a linking group of a significant length which would allow the "display moiety" of the "fusion polypeptide" to react for the purposes of the invention (Remarks of October 31, 2003, page 30, third full paragraph). See also, claim 37 wherein "L" may be  $-CH_2-$  ( $x, y, z = 0; w = 1$ ) and claim 39.

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**c)** There is no enabling written description in the specification of how "a reaction product of a reactant ligand and a fusion polypeptide" is prepared (see page 13 of the specification).

**5)** Claims 36-39 are again rejected under 35 U.S.C. 103(a) as being unpatentable over each of **a)** Mrksich (Chem. Soc. Rev. 2000) or Yousaf et al (JACS 1999) taken in combination with **b)** the admitted prior art as set forth at page 15 of the specification for the reasons set forth in paragraphs **9)** and **11)** of the May 28, 2003 Office action.

Applicant's arguments filed October 31, 2003 have been fully considered but they are not persuasive. Applicant basically argues that there is no motivation to substitute one specific binding ligand pair for another equivalent pair in the products of references **a)**. This argument is unpersuasive for the reason that references **a)** describe a variety of specific ligand binding pairs which are useful for attachment through linking groups to gold surfaces (as described in the instant claims) thus leading one skilled in the art to expect that one well known specific ligand binding pair could be substituted for another equivalent pair, as claimed, in the products of references **a)**. See Mrksich: abstract; page 269, the first paragraph under "3 Biospecific recognition of protein"; page 269, the second column, the last ten lines before "Enzymatic modification of substrate"; page 272, "Conclusions and outlook"; Yousaf et al: page 4287, the first column, the first sentence after structure **3**; Figure 4. Thus, in the absence of evidence to the contrary, it would be expected that one well known specific binding pair member could be substituted for another, as claimed, to obtain a similarly useful reagent for the analysis of the corresponding complementary member of the specific binding pair. Criticality has not been established for the use of the particular "reaction product" of claim 36 as one member of a specific binding pair. Applicant is queried as to whether the "reaction product of a reactant ligand and a fusion polypeptide" of claim 36 is considered to be a novel product.

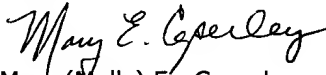
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6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

January 12, 2004

  
Mary (Molly) E. Ceperley  
Primary Examiner  
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